

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

NEW ENGLAND CARPENTERS HEALTH
AND WELFARE FUND, individually and on
behalf of all others similarly situated,

Plaintiff,

v.

ASTRAZENECA LP and ASTRAZENECA
PHARMACEUTICALS LP

Defendants.

Civil Action No.: 12-1192

**CLASS ACTION AMENDED COMPLAINT
AND JURY DEMAND**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PARTIES	3
III.	STANDING	5
IV.	JURISDICTION AND VENUE	5
V.	FACTS	6
A.	Branded drug manufacturers have attacked the private prescription drug co-pay system.	6
B.	Cost sharing is critical to the effective functioning of health care in the United States.	9
C.	The routine waiver of cost-sharing obligations, including co-payments and co-insurance, for medical services and products is unlawful.....	10
D.	Health benefit providers use cost sharing to cope with ever-increasing prescription drug costs.	14
1.	Public and private health benefit providers use tiered cost sharing to reduce spending on prescription drugs.	14
2.	Branded drugs are expensive; differentiated cost sharing for branded and generic drugs help health benefit providers and health plan members curtail prescription drug spending.	18
E.	Co-pay subsidies work: health plan members fill prescriptions for branded drugs instead of generics and health benefit providers pay much higher prices for the subsidized prescriptions.	19
F.	Defendants AstraZeneca LP and AstraZeneca Pharmaceutical LPsubsidized health plan members' co-pays for Crestor and Nexium.	22
1.	AstraZeneca's Crestor Savings Card	22
2.	AstraZeneca's Purple Plus Program for Nexium.....	27
G.	Defendants hired OPUS Health and PSKW to administer its co-pay subsidy programs.	30
1.	Until recently, OPUS Health administered the Crestor and Nexium co-pay subsidy programs for AstraZeneca.	31
2.	PSKW currently administers the Crestor and Nexium co-pay subsidy programs for AstraZeneca.....	36

H.	Health benefit providers do not know, and cannot know, when defendants subsidize their members' co-pays.	38
I.	Defendants' co-pay subsidy programs intentionally interfere with the relationship between health benefit providers and their members.	39
J.	Defendants' co-pay subsidy programs involve misrepresentations sent via mail and the wires.	40
1.	Defendants could not run its programs without using the mail and wires.	40
2.	Defendants convey two distinct misrepresentations via the mail and wires.	41
VI.	CLASS ALLEGATIONS	42
VII.	CAUSES OF ACTION	46
A.	Defendants and its respective co-conspirators formed association-in-fact RICO enterprises.	46
B.	Each co-pay subsidy enterprise engaged in and affected interstate commerce.	47
C.	Defendants associated with its respective co-pay subsidy enterprises.	48
D.	The co-pay subsidy enterprises engaged in a pattern of racketeering activity.	48
1.	The co-pay subsidy enterprises engaged in schemes to defraud.	48
2.	The co-pay subsidy enterprises used interstate communications systems to carry out these schemes.	49
E.	The unlawful activity proximately injured plaintiff and the classes.	50
VIII.	DEMAND FOR JUDGMENT	56
IX.	JURY DEMAND	57

I. INTRODUCTION

1. Plaintiff New England Carpenters Health and Welfare Fund brings this proposed class action against defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP for their unlawful prescription co-payment (“co-pay”) subsidy programs. Defendants have paid, and continue to pay, undisclosed kickbacks to privately-insured individuals so that those health plan members choose defendants’ branded drugs Crestor and Nexium instead of less-expensive therapeutic alternatives. Defendants knowingly caused health benefit providers to pay for more prescriptions of these drugs than they otherwise would have, and caused a falsely-inflated drug reimbursement rate to be reported to, and imposed on, members’ health benefit providers for these subsidized prescriptions.

2. Cost-sharing provisions in prescription drug benefit plans unite the financial interests of the health insurer with the interests of its beneficiaries. Requiring health plan members to pay a small portion of the high cost of a branded prescription drug — either a co-pay or co-insurance — provides a reasonable, personal incentive for privately-insured individuals to choose less-costly, usually generic, medications, and drives down the cost of the much larger residual portion paid by the health benefit providers.

3. In response to cost-sharing provisions, defendants began subsidizing members’ co-payments for its key brand name prescription drugs. These subsidies are designed to undermine cost-sharing arrangements. By eliminating or reducing member co-pays for branded drugs, plan members have no incentive to use less-expensive generic drugs, and health benefit providers end up paying for more costly branded drugs. A recent study estimated that these kickbacks will increase health benefit providers’ prescription drug costs by *\$32 billion* over the next ten years.

4. Each co-pay subsidy program is one size fits all, involving a formulaic, rote discount that applies regardless of the details of the patient's cost-sharing arrangements. Presenting a co-pay subsidy card to a pharmacist triggers a secondary form of insurance — provided by the manufacturer — that functionally reduces the price of the drug without disclosing that price reduction to the insurer. Each and every subsidy is calculated and processed electronically; the health benefit plans receive electronic records falsely indicating that the members paid their personal cost-share obligations, yet the manufacturer's digital paper trail discloses the truth — that the copayments were subsidized by the manufacturer.

5. Carpenters and the proposed classes allege two bases for defendants' liability. First, federal racketeering law prohibits this form of insurance fraud. Through agreements with servicing companies, AstraZeneca's routine waiver of co-payments means that the true costs for reimbursement of the routinely subsidized drug are less than represented by the drug manufacturer and pharmacy, and thus the amount of reimbursement imposed on the health benefit plan is inflated. The brand name defendants commit this fraud through its service provider, and the fraud is accomplished through the use of United States mail and wires. This suit seeks damages under 18 U.S.C. § 1964(c) for violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1962 (c) and (d).

6. Second, federal antitrust law prohibits this form of commercial bribery. Under Section 2(c) of the Robinson-Patman Act, a seller cannot lawfully pay undisclosed kickbacks to someone who makes a decision to purchase a product that is paid for by another. 15 U.S.C. § 13(c). Defendants subsidize members' co-pays to induce them to purchase defendants' branded drugs instead of less-expensive therapeutic alternatives; health benefit providers then pay for the

much more expensive branded drugs. Consumers who use defendants' co-pay savings cards or coupons are not told that their insurers are paying much more for defendants' brand-name drugs.

7. This suit seeks damages on behalf of classes of private health benefit providers under section 4 of the Clayton Act (15 U.S.C. § 15) for overpayments caused by defendants' undisclosed kickbacks.

II. PARTIES

8. Plaintiff New England Carpenters Health and Welfare Fund ("Carpenters") is a Massachusetts-based employee welfare benefit plan established and maintained pursuant to Sections 1002(1) and (3) of ERISA, for the purpose of providing health benefits to approximately 22,000 eligible participants and beneficiaries located throughout New England. Carpenters is a jointly administered Taft-Hartley fund, governed by a twenty-member Board of Trustees comprised of laborers and management representatives. Carpenters is part of a regional council of carpenters, the parent organization of all twenty-six local unions within New England. Carpenters' health benefits are funded through contributions from participants, including carpenters, millwrights, pile drivers and floor coverers, based on hours of work performed. During the course of defendants' subsidy schemes, Carpenters paid for much more expensive brand name drugs in circumstances where its members' cost-sharing obligations were not paid by them personally, but were subsidized by defendants. As a result of defendants' illegal subsidies, Carpenters purchased more of defendants' expensive brand name drugs than it otherwise would have. Carpenters was injured as a result of defendants' unlawful conduct.

9. Defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP are corporations organized and existing under the laws of the State of Delaware and have a registered agent in Harrisburg, Pennsylvania. AstraZeneca markets the branded drugs Crestor and Nexium. Defendant AstraZeneca LP distributes Nexium and holds the Nexium New Drug

Application. Defendant AstraZeneca Pharmaceuticals LP distributes Crestor and holds the Crestor New Drug Application. From in or around April 2011 through the present, AstraZeneca began subsidizing plan members' co-pays in order to increase the number of Crestor and Nexium prescriptions purchased by health benefit providers.

10. OPUS Health, a division of Cegedim Relationship Management, is located at 1324 Motor Parkway, Suite 105, in Hauppauge, New York. OPUS Health administers co-pay subsidy programs for Crestor and Nexium, marketed by AstraZeneca. OPUS Health acknowledges that the co-pay card is designed to overcome certain challenges faced by brand name manufacturers, including how to “speed adoption and build market share” and “influence [health care provider] script activity.” A case study available on OPUS Health’s website boasts of helping a pharmaceutical company develop a co-pay program that generated a 300% return on investment. OPUS Health is *not* named as a defendant in this action but is an unnamed co-conspirator.

11. PSKW LLC, located at 1 Crossroads Drive, Third Floor, in Bedminster, NJ, administers co-pay subsidy programs for Crestor and Nexium, marketed by AstraZeneca. PSKW claims to have “invented and built the copay card industry,” and now “works side by side with biopharmaceutical marketers to help build loyalty to their brands.” In part, PSKW does this by offering “a full range of CoPay assistance . . . for use through retail pharmacies,” including automatic point of sale couponing, described as follows:

[F]or those brands that want to automatically apply a CoPay reduction for their patient population, we provide vouchers on demand – a CoPay reduction service provided at retail to each and every filled subscription. This provides the manufacturer with another vehicle and venue to reach the patient with a CoPay assistance offer, just in case the patient has not received an offer through their physician. Being able to reach the patient at the point of sale could be a critical time if there is a chance that the cost of

filling the prescription is too high or if the patient is comparing the brand name option vs. a generic alternative.

PSKW is *not* named as a defendant in this action but is an unnamed co-conspirator.

III. STANDING

12. Plaintiff Carpenters has standing to bring this lawsuit for three independent reasons.

13. First, during the relevant time periods, and for each of the drugs and programs listed below, Carpenters paid for prescriptions in circumstances where defendants' co-pay subsidy was not reflected in the overall reimbursement amount charged by the pharmacy and paid by Carpenters.

14. Second, during the relevant time periods, and for each of the drugs and programs listed below, Carpenters paid for prescriptions where the member's co-pay was subsidized by defendants.

15. Third, during the relevant time periods, and for each of the drugs and programs listed below, Carpenters paid for prescriptions that, but for defendants' co-pay subsidies, would have otherwise been written for and filled with less expensive medications.

IV. JURISDICTION AND VENUE

16. This action arises under section 4 of the federal RICO statute (18 U.S.C. § 1964) and under section 2(c) of the Robinson Patman Act (15 U.S.C. § 13), a 1936 amendment to the Clayton Act (15 U.S.C. §§ 12-27); the Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 18 U.S.C. § 1964 (RICO), and 15 U.S.C. § 15(a) (Robinson-Patman).

17. The activities of the defendants were within the flow of, were intended to, and did have a substantial effect on interstate commerce of the United States. Venue, therefore, lies within this District under 28 U.S.C. § 1391.

18. Venue is also proper under the special venue provisions of the federal racketeering and antitrust laws, 18 U.S.C. § 1965 and 15 U.S.C. § 22, as defendants AstraZeneca LP and AstraZeneca Pharmaceuticals are headquartered in this District and transact business within this District.

V. FACTS

A. **Branded drug manufacturers have attacked the private prescription drug co-pay system.**

19. Branded drug manufacturers have attacked the private prescription drug co-pay system by subsidizing plan members' co-pays in order to undermine cost-sharing arrangements between health benefit providers and those they insure. These co-pay subsidy programs reduce or eliminate individuals' co-pays regardless of their financial need.¹ Whether characterized as coupons, rebates, subsidies or kickbacks, these payments to plan members interfere with health plans' cost-sharing provisions and intentionally influence prescription drug choice. The programs are designed, quite specifically, to reduce or eliminate privately-insured individuals' personal payment obligations so that they choose the brand name drug and their health benefit providers foot the bill.

20. Although co-pay subsidy programs vary as to the drugs covered and the specific amount of the subsidy or rebate, all programs work the same way. Individuals enroll in drug-specific programs online.² Individuals provide basic information (name, address, and whether they have private health insurance coverage) and the drug company mails them a wallet-size card that included instructions to pharmacists regarding how to process covered prescriptions. Some

¹ Co-pay subsidy programs are, by definition, primarily or exclusively for privately-insured individuals.

² In the infancy of these programs, drug companies gave co-pay subsidy cards to doctors and pharmacists, who in turn gave the cards to patients. Today, some cards are still distributed this way, but most are available online.

drug companies allow individuals to immediately print temporary cards using their home computers.

21. Members then present their card at the pharmacy with a prescription, and the pharmacist processes the prescription according to the instructions on the card. The pharmacist enters information into the computerized data management system in order to submit a claim, first keying in the patient's health insurance information in the primary insurance field. Insurance information regarding the transaction for that particular individual and his/her insurer is transmitted back to the pharmacist from the insurance company or its pharmacy benefit manager ("PBM"), including information about the member's co-pay or co-insurance obligation. The pharmacist then enters information from the co-pay card system into the secondary insurer field. Information regarding the extent of the co-pay subsidy or rebate is similarly computed, but only after the patient's primary insurance is processed (and billed).

22. The pharmacist and PBM use the reimbursement benchmark, which the brand name drug company provides to the reporting agency, to calculate the usual charge (*i.e.*, unreduced by the amount of the subsidy) to the health benefit insurer for the procurement of that prescription drug. The pharmacist and PBM do so without advising the insurer that, at the same time, the plan member's personal cost-share obligation is being picked up by the drug's manufacturer. As a result, the private health benefit provider pays for the medication at its usual (but in fact now inflated) cost, and it does so without being told that the usual cost-share obligation has not been paid by the enrollee, but rather by the brand manufacturer.

23. In effect, defendants bribe plan members to choose its branded drugs over less-expensive therapeutic alternatives in order to get the health benefit plan to pay for the bulk of the cost of its more expensive branded drugs. From the member's perspective, the branded drug and

therapeutic alternatives cost close to, if not exactly, the same amount. But the price of the health benefit plan's share of the therapeutic alternative with the lower co-pay and the branded drug with the higher co-pay may differ by a factor of ten.

An Example: A brand drug company offers a co-pay card giving privately-insured individuals the opportunity to save up to \$25 off their cost share for each prescription filled for a particular, and expensive, medication for chronic illness. The plan member brings the co-pay card to his pharmacy and provides his insurance card and co-pay card to the pharmacist. The pharmacist processes information from the insurance card and transmits it to the PBM. The PBM recognizes the drug as a TIER 3 brand drug for the plan member and relays a \$70 obligation to the insurer and a \$30 co-pay obligation to the patient.

In a separate transaction, the pharmacist processes information from the co-pay savings card or coupon. The co-pay card program administrator recognizes the \$30 co-pay and covers \$25 thereof, leaving \$5 for the patient to pay out of pocket (while the pharmacy charges the remaining \$25 to the manufacturer through the co-pay card program administrator). The insurer is required to pay for the branded drug as if it were priced at \$100, even though the usual cost for these subsidized transactions is \$75, and even though there are equally appropriate, less expensive medications available at prices around 1/3 the cost of the branded drug.

24. By their terms, Novartis's co-pay subsidy programs (i) apply to individuals who are privately insured under a prescription drug plan that requires personal cost sharing by the member for retail prescription drugs such as those covered by the co-pay subsidy programs, (ii) undermine the contractual insurance arrangement between the insurer and the insurer's member by reducing or eliminating the personal cost-share feature of the insurance contract, (iii) cause the health benefit provider to pay for more units of expensive co-pay subsidy drugs than it would have if the defendants had not interfered with the parties' performance of the contract, and (iv) increase the overall burden on the plan for providing benefits to its members.

25. Co-pay subsidy programs are also effectively a form of secondary insurance whereby defendants agree to cover a portion of the privately-insured individual's prescription

drug expenses. Prescription drug benefit plans, along with the formularies under which they operate, set forth appropriate balances in coverage terms, means of access, payment obligations and cost-sharing provisions for medications. Prescription drug insurance contracts — whether they are wholly private plans, or plans that are privately administered but publicly subsidized (such as Medicare Part D plans or managed Medicaid drug plans) — are governed by myriad federal and state laws and regulations which ensure that the plans properly balance the availability of prescription drugs on sensible financial terms. Defendants' co-pay subsidies, function as unregulated secondary health insurance that, after payment by the primary insurer, swoop in to relieve the plan member of specifically-designed *personal* financial obligations. By doing so, the co-pay schemes fundamentally change the nature of the regulated relationship between health insurers and members. Although defendants' co-pay subsidies function as a form of secondary insurance, defendants do not comply with the myriad laws governing the provision of health insurance.

B. Cost sharing is critical to the effective functioning of health care in the United States.

26. In most economic systems, the person who *selects* the product or service is also the person who *pays* for the product or service. Health care is a big, notable exception. Typically, a physician or other health care provider (in consultation with the patient) *chooses* the medication or medical procedure, the patient *receives* the care or consumes the medication, and a public or private health benefit provider *pays* for the services and medication. The payer is separated from those who make the purchasing decision. Without cost-sharing provisions — such as percentage co-insurance or graduated co-pays — those choosing the prescription drugs (individual patients in consultation with their physicians) have little or no incentive to choose less costly drugs.

27. Public and private health insurance relies on cost sharing to re-align the interests of patients, health care providers, and health benefit providers. Although cost-sharing techniques vary by type and amount, they all have the singular purpose of imposing a personal financial obligation on the covered individual in order to encourage price sensitivity and achieve the range of acceptable balance between coverage and cost. Insured individuals often face point-of-service charges for medical services and prescription drugs. These include deductibles (amounts that must be paid before some or all services are covered), co-payments (fixed dollar amounts), and/or co-insurance (a percentage of the charge for services). Health benefit providers impose different degrees of cost sharing for different services: annual deductibles for medical services, a separate deductible for prescription drugs, hospital and outpatient co-insurance, co-pays for physician office visits, and/or out-of-pocket maximum amounts.

28. Cost sharing is therefore fundamental to almost all medical spending in the United States. Whether it be for hospital, physician, dental, or other health care provider services, for employer-sponsored or individual plans, for medical procedures, or for prescription drugs, numerous forms of cost sharing are imposed as a critical component of public and private health plans in order to carefully incentivize cost-conscious use of medical services and products while at the same time affording appropriate access to medical care.

C. The routine waiver of cost-sharing obligations, including co-payments and co-insurance, for medical services and products is unlawful.

29. Recognizing the ubiquity and necessity of cost sharing, federal and state statutes declare the practice of routinely waiving co-payment obligations for medical services and products to be unlawful.

30. First, routinely waiving co-pays constitutes financial inducements that are deemed illegal kickbacks. The waiver is in effect a form of payment that induces the use of medical

services or products offered by the party that routinely waives co-pays. The routine waiver of co-pays amounts to health care fraud and is criminal.³ In the public arena, physicians, hospitals, and medical products providers who receive payment through Medicare or Medicaid programs and routinely waive co-payments or deductibles may be held in violation of federal and state anti-kickback statutes. The federal anti-kickback statute prohibits the payment of remuneration (any kickback, bribe or rebate) when it is knowingly paid to induce business that will be paid for by a federal health care program.⁴ And the routine waiver of co-payments in the Medicare and Medicaid areas forms the basis for a violation of the False Claims Act and the Civil Monetary Penalties Law.⁵

31. Second, the routine waiver of co-payments constitutes a form of insurance fraud.⁶ When cost sharing is routinely waived, the true acquisition cost for the medical service or product is not the stated or reported price being charged to health benefit providers, but rather the price *after deduction for the routinely waived co-payments*. The unlawfulness of this form of insurance fraud is well-known to physicians of any stripe, hospitals, and other health care providers. Physicians and other providers have been criminally prosecuted for routinely waiving co-payments yet still charging the insurer the inflated, pre-waiver price. The American Medical

³ 18 U.S.C. § 1347: Health care fraud (“Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. . . . [A] person need not have actual knowledge of this section or specific intent to commit a violation of this section.”); 18 U.S.C. § 1349: Attempt and conspiracy (“Any person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those prescribed for the offense . . .”).

⁴ 42 U.S.C. § 1320a-7b(b).

⁵ See 42 U.S.C. § 1320a-7a; 31 U.S.C. § 3729.

⁶ See, e.g., *Kennedy v. Connecticut Gen. Life Ins. Co.*, 924 F.2d 698, 699 (7th Cir. Ill. 1991) (appellant was required to collect co-payments from the insured patients if he wished to receive payment under an insurance plan that required co-payments: “Providers of medical care may seek to increase their business by promising to waive [] co-payments. Patients prefer the lower outlays, but waivers annul the benefits of the co-payment system.”); *id.* at 702 (“[a]llowing the provider to ‘pay’ the co-payment to himself is just another way to describe waiver of co-payments”).

Association has long issued the following warning: “physicians should be aware that forgiveness or waiver of copayments may violate the policies of some insurers, both public and private. . . . Routine forgiveness or waiver of copayments may constitute fraud under state and federal law.”⁷

32. Third, the terms of AstraZeneca’s co-pay subsidy programs would violate federal and state anti-kickback statutes. The federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)(2)) provides:

Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly . . . to any person to induce such person . . . to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

33. The Massachusetts False Health Care Claims Act (MASS. GEN. LAWS ch. 175H § 3) similarly provides:

[A]ny person who offers or pays any remuneration, including any bribe or rebate, directly or indirectly . . . to induce any person to purchase . . . any good, facility, service, or item for which payment is or may be made in whole or in part by a health care insurer, shall be punished by a fine of not more than ten thousand dollars, or by imprisonment in a jail or house of correction for not more than two and one-half years or in the state prison for not more than five years, or by both such fine and imprisonment, and may be held liable in a civil action.

34. Defendants knowingly offer and pay remuneration in the form of a co-pay subsidies to patients in order to induce them to purchase defendants’ brand name drugs. The federal government has acknowledged that co-pay subsidy programs may well violate the federal antikickback statute.⁸

⁷ American Medical Association Opinion 6.12, issued June 1993, *available at* <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion612.page>.

⁸ See Publication of OIG Special Advisory Bulletin in Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70624 (Nov. 22, 2005) (“[W]e conclude that pharmaceutical manufacturer PAPs [Prescription

35. AstraZeneca knows that subsidizing a co-payment for a drug paid for by the federal government or a Massachusetts resident would violate the statutes. Although defendants' programs purport to exclude Medicaid and Medicare recipients and Massachusetts residents in the fine print, on information and belief, the programs have been, and are being, used by persons who participate in those federal and state programs. For example, many individuals are enrolled in and receive prescription drugs under Medicare Part D; but because Medicare Part D benefits are sponsored by private health benefit providers, individuals enrolling in defendants' programs may report themselves as privately insured, *not* as Medicare patients. Similarly, many Medicaid patients receive their care through managed Medicaid programs run by private health insurers, not state agencies; again, when enrolling in defendants' co-pay subsidy programs, these individuals may report themselves as privately insured simply by clicking the appropriate "no" buttons on defendants' website.

36. If Medicare's ban on co-pay coupons were not enforced, costs to the Part D program would increase by \$18 billion over the period from 2012 to 2021.

37. Massachusetts is the only state that statutorily bans co-pay coupons for private payers. Were it to repeal that law, a recent study suggests that prescription drug costs for employers and other plan sponsors in Massachusetts would increase by \$750 million by 2021. Many states that do not explicitly prohibit these programs will see similar — or even larger — increases. For example, Illinois plans are expected to spend nearly \$1.4 billion extra on prescription drug costs as a result of co-pay coupons or programs during that time; Florida, New

Assistance Programs] that subsidize Part D cost-sharing amounts present heightened risks under the antikickback statute.”).

York, California and Texas will spend an extra \$2 billion each in the next decade as a result of the same programs.⁹

D. Health benefit providers use cost sharing to cope with ever-increasing prescription drug costs.

38. Cost sharing has particular importance in the coverage for prescription drug benefits. In 2000, prescription drug spending in the U.S. exceeded \$142 billion. By 2009, spending ballooned to more than \$300 billion. This increase in drug spending is in large part due to high and rising prices for the most well-known and most often used brand name drugs. In recent years, the price of the most widely used brand name drugs increased annually at approximately 6% to 9% — two or three times the general rate of inflation. Both of the drugs at issue in this action has seen significant price increases in recent years.

1. Public and private health benefit providers use tiered cost sharing to reduce spending on prescription drugs.

39. For both public and private health benefit providers, prescription drug cost sharing is widely and effectively used, and has been for many years.

40. In the public realm, beneficiaries under Medicaid have, for years, been required to pay a portion of the cost of their medications, despite the fact that Medicaid eligibility is limited to low-income and disabled individuals. Similarly, even beneficiaries under Medicare Part B — generally the elderly receiving critical physician or in-home services — have been required to share the costs of their medications. And, more recently, beneficiaries under Medicare Part D are required to make co-payment or co-insurance payments under terms specified by Medicare Part D plan sponsors.

⁹ Visante, “How Copay Coupons Could Raise Prescription Drug Costs By \$32 Billion Over the Next Decade”, Nov. 2011, *available at* <http://www.pcmnet.org/images/stories/uploads/2011/Nov2011/visante%20copay%20coupon%20study.pdf> (“Visante Study”), at 13-15.

41. Most health insurance in the United States is provided by private health benefit providers. In the private realm, cost sharing for prescription drugs is similarly widespread. Under private health insurance plans, individuals and employers pay premiums to health benefit providers and, in turn, the health benefit providers agree to pay all or a portion of the cost of needed medical services and products.¹⁰ Well over 95% of covered employees in employer-sponsored private health benefit plans have prescription drug benefits. More often than not, the form of cost sharing is a co-payment rather than co-insurance, although co-insurance has steadily increased over time.

42. Drug benefit cost-sharing provisions have evolved over the decades, with the key innovation being the differentiation of co-payments among differing drugs. When drug insurance was first introduced, the plan member typically paid the same co-insurance (or co-pay) rate for any drug. Over time, that changed, and the price now depends on the “tier” in which the drug is placed. The early tiered plans typically had only two tiers, but most plans now have three or more tiers. In recent years, an increasing number of plans have created a fourth tier of drug cost sharing, which may be used for lifestyle drugs or expensive biologics:

¹⁰ In the United States, most private health insurance is paid at least in part paid for by employers, although it is also common for employees to contribute to the cost of their premiums. Truly individual health insurance policies may also be purchased.

Generic drugs: A drug product that is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.

Preferred drugs: Drugs included on a formulary or preferred drug list; for example, a brand name drug without a generic substitute.

Non-preferred drugs: Drugs not included on a formulary or preferred drug list; for example, a brand name drug with a generic substitute.

Fourth-tier drugs: New types of cost-sharing arrangements that typically build additional layers of higher copayments or coinsurance for specifically identified types of drugs, such as lifestyle drugs or biologics.

Brand name drugs: Generally, a drug product that is covered by a patent and is thus manufactured and sold exclusively by one firm. Cross-licensing occasionally occurs, which allows an additional firm to market the drug. After the patent expires, multiple firms can produce the drug product, but the brand name or trademark remains with the original manufacturer's product.

43. The number of plans requiring some form of cost sharing that differentiates between forms of drugs has steadily increased, but has plateaued in recent years. Almost 90% of privately-insured individuals have some formula for tiered cost-sharing formula: over 75% are enrolled in plans with three, four, or more tiers of cost sharing for prescription drugs.

44. A drug's tier placement largely depends on its cost: Tier 1 drugs are less expensive, usually generic, drugs. More expensive, usually brand name, drugs are placed on higher tiers. Health benefit providers encourage members to choose Tier 1 drugs by imposing a lesser co-pay than that imposed for Tier 2 drugs. Tiered co-payments and co-insurance (which is a percentage of the overall cost of the drug at retail) thereby provide reasonable personal financial incentives to individuals to use equally effective, but less costly, medications. If a drug is placed on Tier 1, the member pays the pharmacy a relatively small co-payment. If the drug is placed on Tier 2, the co-payment or coinsurance obligation increases. The difference in the co-payment/coinsurance between Tier 2 and Tier 1 incentivizes the plan member to choose the less

costly medication. If a drug is a Tier 3 drug, a therapeutic or generic equivalent will invariably exist for the medication in Tier 2 and/or Tier 1.

45. Another major, long term trend has been the increasing *amount* of the co-payment or coinsurance required. Over the last decade, average retail co-payment levels increased by about 62%. Average co-payments for Tier 2 drugs increased by about 127%. Average co-payments for Tier 3 drugs increased the most, from about \$17.53 in 1998 to about \$42.95 in 2009, an increase of about 149%. As expected, the 2009 average retail co-payment for Tier 4 drugs is even greater, at \$62.11.

46. Widespread use of cost sharing for prescription drugs, the increasing trend of multi-tier cost sharing and the increasing amounts for co-payments and co-insurance are, of course, no accident. Although other forms of prescription drug cost reductions may have more dramatic results — including the market entry of AB-rated generic equivalents — cost sharing has defined, measurable results. Cost sharing provides personal financial incentives to plan members to select the most cost-appropriate medications; these incentives work.

47. Patients — and to a lesser extent, their doctors — are sensitive to differences in co-payment requirements, particularly for maintenance drugs that they anticipate taking for long or indefinite periods of time. According to a 2007 literature review published in the Journal of the American Medical Association, *every 10% increase in cost sharing (through co-payments or co-insurance) reduces drug spending by 2 - 6%*. And drug companies are well aware that plan members' consider co-pay differences when choosing prescription drugs: “[t]he patient, I will tell you, is economically very, very sensitive to co-pays, and a \$5, \$10, \$20, \$25 co-pay matters,” says Abbott Laboratories Chief Executive Miles White.¹¹

¹¹ Event Brief of Q2 2009 Abbott Earnings Conference Call – Final, FD (Fair Disclosure) Wire (July 15, 2009).

2. Branded drugs are expensive; differentiated cost sharing for branded and generic drugs help health benefit providers and health plan members curtail prescription drug spending.

48. Generic drugs thus play a critical role in health benefit providers' attempts to curb ever-escalating prescription drug costs. Generic drugs are almost always significantly less expensive than their branded counterparts. On average, generic prescriptions cost payers \$16, preferred brand prescriptions cost \$118, and non-preferred brands cost \$124. Tiered cost-sharing provisions thus incentivize generics by imposing a lower co-pay or co-insurance for generics than for brands.

49. AB-rated generics are, by definition, substitutable for their branded equivalents. All fifty states have laws that permit pharmacies to substitute AB-rated generics for their branded counterparts when an AB-rated equivalent is available. Health benefit providers create strong incentives for plan members to demand generic drugs by imposing different co-pays for branded and generic drugs. Consequently, more than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. 2010 IMS industry data — the industry's gold standard — reflects that, on average, AB-rated generics capture 80% of the brand's sales within the first six months.

50. In addition to AB-rated generics, a brand name drug may also have generic therapeutic alternatives. Therapeutic alternatives are *not* bioequivalent to their brand-name counterparts, but are alternative medicines that treat the same medical condition in a similar way.

51. As an example, Pfizer's blockbuster drug Lipitor belongs to a therapeutic class of drugs called "statins" used to treat high cholesterol. But because statins work in similar ways, a patient and/or physician may determine that another statin, such as generic simvastatin, lovastatin, and pravastatin, is a sensible cost-effective alternatives — particularly since (without

a co-pay subsidy) the cost to the patient by reason of the tiered co-payment system would be much higher for Lipitor than for a generic statin.

E. Co-pay subsidies work: health plan members fill prescriptions for branded drugs instead of generics and health benefit providers pay much higher prices for the subsidized prescriptions.

52. These kickbacks work. According to a 2011 study undertaken for the Pharmaceutical Care Management Association and based on evidence from drug coupon administrators, “25% of [co-pay] coupon use results in a couponed drug being used instead of a preferred brand or generic that might have been used in the absence of the coupon.”¹² More than 100 million prescriptions were associated with co-pay coupons in 2010, accounting for 11% of brand prescriptions.¹³ These numbers will grow exponentially: at current trends, the number of prescriptions associated with co-pay subsidy programs will increase by 15% per year, reaching 500 million prescriptions and approximately 50% of non-specialty brand prescriptions by 2021.¹⁴ All told, employers and other plan sponsors will likely spend an extra \$32 billion on prescription drugs as a result of these co-pay subsidy programs over the next decade.¹⁵

53. It is estimated that pharmaceutical companies spend \$4 billion on co-pay cards and coupons annually.¹⁶ Drug manufacturer Amgen has stated publicly that spending on its co-pay subsidy programs amounts to about *1% of its total product sales*; in the first quarter of 2010, Amgen spent \$35 million on co-pay subsidy programs. This amount is likely to increase as more co-pay programs are created and more plan members take advantage of existing programs.

¹² Visante Study at 11. (“Visante study”).

¹³ *Id.* at 12.

¹⁴ *Id.*

¹⁵ *Id.* at 3, 13-15.

¹⁶ Matthew Herper, *How Bargain Lipitor Could Raise Health Costs*, FORBES.COM, <http://blogs.forbes.com/matthewherper/2011/03/16/how-bargain-lipitor-could-raise-health-costs/> (last visited Mar. 2, 2012) (citing Mason Tenaglia, managing director of the Amundsen Group, a consulting firm that has studied the cards). *See also* Visante Study at 6.

54. Brand-name pharmaceutical manufacturers know that these co-pay subsidy programs work: these programs are now a regular part of life cycle planning for branded drugs, typically launching two to three years before AB-rated generic equivalents of the brand name drug are expected to enter the market. The manufacturer tries to maximize the number of prescriptions written by physicians, filled by members, and paid for by both members and health benefit providers before pharmacies begin automatically substituting the AB-rated generic equivalents for the brand name drug.

55. Health benefit providers have seen significant increases in the number of prescriptions filled for brand name drugs that have co-pay subsidy programs. Recently, co-pay subsidy administrators have anecdotally reported that their unnamed clients, manufacturers of branded drugs, earn between a 4:1 and 6:1 return on their investments in these programs.

56. The attack on prescription drug co-payment system is open and notorious. Large branded drug companies reflexively subsidize co-payments for many brand name drugs simply because they are nearing patent expiry. Co-payment subsidy administration has become a cottage industry. Program administrators boast about the effective and efficient methods by which they have wiped out the personal financial incentives of plan enrollees to select, in consultation with their physicians, less costly medications.

57. Drug companies, including defendants, not only determine the price at which wholesalers or large retailers will purchase prescription drugs from them, but also control the reimbursement benchmark used to determine the amount to be paid for the drugs by public and private health benefit providers. Either by directly determining the so-called average wholesale price (or “AWP”) or by determining a related price benchmark known as the wholesale acquisition price (or “WAC”) that reporting agencies use to mathematically determine the AWP,

branded drug manufacturers cause to be published the widely-used and nearly ubiquitous benchmark prices for payments and reimbursements that health benefit providers make to pharmacies for branded, retail-channel drug products.

58. Branded drug manufacturers, including defendants, know that the reported benchmark that they control is required to be a reasonably fair estimation of the actual price for the ingredient cost of the drug to the retailer. When a prescription for a privately-insured individual is filled at the retail level (*i.e.*, a pharmacy), the pharmacy charges the member's plan for the ingredient cost of the drug plus a dispensing fee. The amount to be charged for the ingredient cost is based on a percentage discount from the benchmark (*e.g.*, AWP minus 14% for all branded drugs). Thus, the stated benchmark represents the price that all participants — the health benefit provider, its pharmacy benefit manager, the pharmacy and the manufacturer — understand is a reasonable estimate of the actual cost to the pharmacy on which the payer's reimbursement to the pharmacy is based. Of course, if a cost-sharing provision exists for the member's prescription drug plan, then the cost share (*e.g.*, co-payment or co-insurance) is deducted from the amount owed by the plan to the pharmacy and is imposed on the member as a payment to the pharmacy. However, for subsidized co-pays, the true benchmark is less, resulting in an inflated payment by the health insurers.

59. Routinized co-pay subsidy programs constitute commercial bribery because the programs pay undisclosed kickbacks to plan enrollees to select expensive medications that are paid for by prescription drug benefit providers.

60. Routinized co-pay subsidy programs constitute insurance fraud because routine waiver of co-payments reduces true acquisition costs, yet drug manufacturers withhold co-

payment information, do not decrease the applicable reimbursement benchmark for the drugs, and cause inflated payments to be imposed upon private prescription drug benefit providers.

F. Defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP subsidized health plan members' co-pays for Crestor and Nexium.

61. Defendants designed and implemented the programs described below (collectively, the “co-pay subsidy programs”), relating to the brand name drugs Crestor and Nexium (collectively, the “co-pay subsidy drugs”).

62. Each of Defendants' co-pay subsidy programs described below alters the carefully calibrated co-payment system negotiated by health benefit providers and their members. Each is intended to steer unsuspecting members toward more expensive brand name drugs when less expensive therapeutic alternatives are available in generic form, with generic price tags.

1. AstraZeneca's Crestor Savings Card

a. AstraZeneca faced substitution competition from therapeutic alternatives just three years after the launch of Crestor.

63. On August 12, 2003, the FDA approved AstraZeneca's statin Crestor (rosuvastatin calcium) to treat hypercholesterolemia and mixed dyslipidemia. Long before the drug was approved, however, AstraZeneca's sales force had already hit the ground running, positioning Crestor, as Adele Gulfo, AstraZeneca's Vice President of Cardiovascular Therapy told investors that year, “to be one of the fastest and most well received primary care launches in the history of the pharmaceutical industry.”¹⁷

64. One month prior to approval, three-quarters of AstraZeneca's targeted cardiologists were aware of the new product, and within five days of approval, the company had orders from over 90% of pharmacies; it reached fully stocked status in just eight days.¹⁸

¹⁷ AstraZeneca PLC Annual Business Review 2003 – Final, FD (Fair Disclosure) Wire (Oct. 2, 2003).

¹⁸ *Id.*

The company rapidly deployed a field sales force with an early doctor sampling program, so that in the week leading up to the official field launch, AstraZeneca was able to reach almost three-quarters of what it considered to be its highest opportunity prescribing doctors.¹⁹

65. As AstraZeneca explained to investors, Crestor was staged to make billions of dollars in the highly lucrative statin market:

Let me remind you that this type of momentum was unleashed in a market with tremendous opportunity. As you know, the U.S. statin market is valued at more than \$13 billion, generates close to 130 million prescriptions annually, and is projected to grow at over 160 million prescriptions by 2006. This represents year-on-year growth of over one billion dollars in sale and 10 million total prescriptions. These are pretty significant figures in a market that some consider to be satisfied and slowing down.²⁰

66. AB-rated bioequivalent rosuvastatin will not be available until 2016. Less expensive therapeutic alternatives to Crestor include pravastatin (Pravachol) and simvastatin (Zocor). Generic pravastatin entered the market in April 2006 and generic simvastatin entered in June 2006. Given the high cost of brand maintenance cholesterol-reducing drugs, cost-sharing mechanisms in prescription drug plans were developed to incentivize substitution, where appropriate, within the therapeutic class of statins.

b. In the wake of substitution competition from less expensive therapeutic alternatives, AstraZeneca created the Crestor Savings Card co-pay subsidy program.

67. To combat the substitution competition it was facing from less expensive therapeutic alternatives, on or around April 15, 2011, AstraZeneca began offering the Crestor Savings Card:²¹

¹⁹ *Id.*

²⁰ Adele Gulfo, AstraZeneca's Vice President of Cardiovascular Therapy, AstraZeneca PLC Annual Business Review 2003 – Final, FD (Fair Disclosure) Wire (Oct. 2, 2003).

²¹ <http://www.crestor.com/c/crestor-patients/crestor-savings/savings-card.aspx> (Dec. 7, 2011).

CRESTOR Savings Card

[Print your Savings Card](#)

[Unable to print?](#)

Why pay more? With the CRESTOR Savings Card, get CRESTOR for only \$18 per prescription.*

To start saving, simply [print your CRESTOR Savings Card](#). It's already activated. Just click the link above and take it with your prescription to the pharmacy.

After requesting your CRESTOR Savings Card, you'll be invited to sign up for CRESTOR support.

You are not eligible for this if:

- You receive CRESTOR by mail,
- Are a resident of Massachusetts, or
- Purchase your prescription under Medicaid, Medicare, or similar federal or state programs.

*Please see full [eligibility details](#).



68. Until recently, AstraZeneca's patient website explained that, by using the Card, "[c]ommercially insured patients receive[d] savings on out-of-pocket costs that exceed[ed] \$25 (up to a \$75 savings limit) on each of [the patient's] next 12 prescriptions (up to 30 tablets) of CRESTOR."²²

69. In late 2011 or early 2012, AstraZeneca revised the terms governing the Crestor Savings Card, which now provides commercially-insured patients with savings on out-of-pocket costs that exceed \$18 (up to a \$50 savings limit), on each of their next twelve prescriptions.

70. The Crestor Savings Card is not a need-based program. Privately insured members who fill their prescriptions at a pharmacy can participate regardless of their income or financial need, so long as their cost share expense exceeds \$18 per prescription.

71. At one point, patients were required to activate their Crestor Savings Cards by entering their name, address, e-mail address, gender and date of birth into a short, online form on

²² The offer expires fourteen months from the time of first use.

AstraZeneca's website: www.crestor-patients/crestor-savings/card-activation/index.aspx. Now, the website states: "[t]o start saving, simply print your CRESTOR Savings Card. It's already activated. Just click the link above and take it with your prescription to the pharmacy."

72. AstraZeneca even once offered a Cost Estimator tool that calculated the estimated out-of-pocket cost to the patient for his or her Crestor prescription. All the patient had to do was select a state of residence and insurance plan from a drop-down list, and the website generated a certificate titled "Cost Estimator Results," which estimated the patient's cost share percentage. The source of this data was a company called Fingertip Formulary, which explains on its website that its "goal is to help pharmaceutical clients understand the managed care landscape and improve their sales and marketing efforts."

73. The Crestor Savings Card is advertised directly to individuals through full-color advertisements in magazines and newspapers with both nationwide and local circulation. For example, the September 19, 2011 issue of Newsweek featured a color advertisement inviting readers to "[l]earn how to SAVE ON CRESTOR" and "[p]rint out [their] CRESTOR Savings Card at CRESTOR.com/savings." Above a picture of the Crestor Savings Card, the advertisement boasted that commercially-insured patients could "[g]et [their] CRESTOR prescription[s] for just \$8 more than the copay of a generic statin, with the CRESTOR Savings Card." Similar full-page advertisements appeared in the September 12, 2011 issue of The Washington Post and the December 7, 2011 issue of the Sun Sentinel, Palm Beach Edition.

74. On AstraZeneca's website for healthcare professionals, doctors were formerly encouraged to "[h]elp eligible patients save on CRESTOR prescriptions with the CRESTOR Savings Card." They are now invited to "[f]ind money-saving offers that can help [their]

patients pay for their medication,” and are told that “[w]ith the CRESTOR Savings Card, patients can get CRESTOR for just \$8 more than the copay of a generic statin.”²³

c. AstraZeneca’s Crestor Savings Card program specifically provides that it does not apply to Medicare or Medicaid patients, or to residents of Massachusetts.

75. To enroll in the Crestor Savings Card program in or around 2011, a patient had to provide his or her mailing address and was asked, “Is your prescription paid for in part by any government, state, or federally funded prescription benefit program, including Medicaid or Medicare Part D?” If a patient indicated that he or she was a resident of Massachusetts or answered “Yes,” to the question, he or she was told, “Based on the information you provided, you’re not eligible for the CRESTOR Savings Card. You are not eligible for this offer because you receive CRESTOR by mail, are a resident of Massachusetts, or purchase your prescription under Medicaid, Medicare, or similar federal or state programs.”

76. With recent changes to AstraZeneca’s website, patients may now print their Crestor Savings Cards directly, without providing any personal information. The website states: “[a]fter requesting your CRESTOR Savings Card, you’ll be invited to sign up for CRESTOR Support. You are not eligible for this if . . . [you a]re a resident of Massachusetts, or [p]urchase your prescription under Medicaid, Medicare, or similar federal or state programs. As stated, these restrictions appear to apply only to something called the Crestor Support program, and not to the Savings Card itself.

77. Under “Patient Eligibility,” however, AstraZeneca states that the program is “not valid for prescriptions purchased under Medicaid, Medicare, or similar federal or state programs Offer is void in MA and where prohibited by law, taxed, or restricted.” The website’s

²³ <http://www.crestortouchpoints.com/>.

“Patient Instructions” section makes clear that only [c]ommercially insured patients” are eligible to receive savings under the program.

2. AstraZeneca’s Purple Plus Program for Nexium

a. AstraZeneca faced competition from less expensive therapeutic alternatives after the launch of Nexium.

78. On February 20, 2001, the FDA approved Nexium (esomeprazole magnesium) to treat erosive esophagitis and gastroesophageal reflux disease. Initial sales placed Nexium among the top five drugs by sales in the United States in 2003.

79. Over the next three years, sales of Nexium increased by double-digit percentages each year, reaching more than \$4 billion in 2006 and making Nexium the number two drug in the country.²⁴ AstraZeneca bragged to its investors that Nexium had attained “the second most successful product launch of all time” and was “the market leader among gastroenterologists.”²⁵

80. In 2010, Nexium became the number one drug in the country, with sales of over \$5 billion.

81. Less expensive therapeutic alternatives to prescription Nexium include prescription omeprazole (Prilosec) and prescription ranitidine (Zegrid).

b. In the wake of substitution competition from less expensive therapeutic alternatives, AstraZeneca created the Purple Plus Savings Card co-pay subsidy program.

82. To combat the substitution competition it was facing from less expensive therapeutic alternatives, on or around August 25, 2011, AstraZeneca began offering the Nexium Purple Plus Card:²⁶

²⁴ http://www.drugs.com/top200_2003.html; http://www.drugs.com/top200_2004.html; http://www.drugs.com/top200_2005.html; http://www.drugs.com/top200_2006.html;

²⁵ Tony Zook, AstraZeneca Vice President of Commercial Operations, AstraZeneca PLC Annual Business Review 2003 – Final, FD (Fair Disclosure) Wire (Oct. 2, 2003).

²⁶ <http://www.purplepill.com/taking-nexium/purple-plus-savings-card.aspx> (Dec. 7, 2011).

The NEXIUM Savings Card

With the NEXIUM Savings Card, most patients will pay only \$18*

If you're eligible for the NEXIUM Savings Card, you may save up to \$50 on your next prescription for NEXIUM. Here's how.



- **If you have prescription coverage** and your copay is more than \$18, you may receive up to \$50 in savings each time you fill your NEXIUM prescription (up to 12 fills)†
- **If you do not have prescription coverage**, AstraZeneca will cover the first \$50 of your out-of-pocket cost each time you fill your NEXIUM prescription (up to 12 fills)

This offer is not valid for prescriptions purchased under Medicaid, Medicare, or similar state or federally funded health care programs and is void where prohibited by law, taxed, or restricted. Not valid in Massachusetts.

To obtain a NEXIUM Savings Card, use the "Print now" button below, ask your doctor, or call 1-800-4 NEXIUM.



NEXIUM SAVINGS CARD EXAMPLES

Prescription Coverage

If my copay is...	Can I use the card?	My cost with card	Savings on each prescription with card	Maximum savings with card
\$10	N	\$10	--	--
\$25	Y	\$18	\$7	\$84
\$40	Y	\$18	\$22	\$264
\$60	Y	\$18	\$42	\$504
\$75	Y	\$25	\$50	\$600

83. As the patient website explains: "If you have prescription coverage and your copay is more than \$18, you may receive up to \$50 in savings each time you fill your Nexium prescription (up to 12 fills)." The card is good for twelve monthly prescriptions, but expires fourteen months after it is first used.

84. The Purple Plus program is not a need-based program. It is open to all patients with commercial prescription insurance coverage for Nexium. A patient can print the card directly from AstraZeneca's website without entering any personal information. AstraZeneca

even provides a number of examples showing the amount that patients with different co-pays will save by using the card.

85. The Purple Plus Savings Card is advertised to physicians and directly to individuals through full-color advertisements in magazines with nationwide circulation and on television. For example, the July 10-16, 2010 issue of The Lancet, a journal for healthcare professionals, included a color advertisement regarding “Simple Solutions to Help Your Patients” that included “Support through The Purple Plus™ Savings Card Program.” On August 9, 2010, the Game Show Network aired a commercial for Nexium that included the line “for the majority of patients with prescription coverage for Nexium, it can cost \$30 or less per month.” A similar commercial aired on the same network on September 3, 2010.

c. AstraZeneca’s Purple Plus program specifically provides that it does not apply to Medicare or Medicaid patients, or to residents of Massachusetts.

86. The Purple Plus program’s website states that the “offer is not valid for prescriptions purchased under Medicaid, Medicare, or similar state or federally funded health care programs and is void where prohibited by law, taxed, or restricted.” It also notes that the offer is “[n]ot valid in Massachusetts.”

d. The Purple Plus card functions as an unlawful form of secondary health insurance.

87. The fine print on the back of the Purple Plus card specifically instructs pharmacists on how to process the card as a form of secondary insurance:

Pharmacist Instructions: For insured, submit this claim to the primary Third Party Payer first, then submit the balance due to Therapy First Plus as a Secondary Payer as a copay-only billing using a valid Other Coverage Code, (e.g. 8). The patient pays first \$18 and card pays the next \$50.

G. Defendants hired OPUS Health and PSKW to administer its co-pay subsidy programs.

88. AstraZeneca depends on cooperation from both pharmacies and program administrators to conduct these co-pay subsidy programs. Defendants compensate both pharmacies and the co-pay benefit administrators for their efforts. Defendants and its co-conspirator administrators process co-pay subsidy claims through a “shadow claims system” that hides the subsidies from health benefit providers.

89. For prescription drugs, plan members present their co-pay cards or coupons along with their health insurance cards (which include the prescription drug plan) at the pharmacy. An individual’s primary insurance is processed first, establishing the plan member’s co-pay or co-insurance amount²⁷ and the price of the drug that will be billed to the health benefit provider.

90. The pharmacist then processes the co-pay card or coupon associated with the co-pay subsidy program. The pharmacist enters into the pharmacy computer information on the co-pay card as though it were a form of secondary insurance. The pharmacist notes the amount of the co-pay that will be subsidized by defendants and convey that information to a co-pay card program administrator, who reimburses the pharmacy on defendants’ behalf.²⁸ The plan member pays out-of-pocket the difference between his or her co-payment (or co-insurance) and the amount subsidized by the defendants. The pharmacist then charges the health benefit provider the full amount of the health benefit provider’s usual payment for the branded drug in question, *i.e.*, the health benefit provider pays an amount for the co-pay subsidy drug’s purchase as if the plan’s member had made full personal payment of his/her cost-sharing obligation.

²⁷ For plan members with a co-insurance responsibility, pharmacists determine the dollar amount to be paid by the member. Sometimes, this amount is referred to, inaccurately, as a “co-pay.”

²⁸ The administrator pays pharmacies for all co-pay subsidies on the manufacturer’s behalf every fourteen to twenty-eight days. The manufacturer repays the administrator on a similar schedule.

91. During a transaction *without* the use of the unlawful co-pay subsidy, the pharmacy reports data to the health benefit provider (or its PBM) that enables the provider to know the claim, drug dispensed, amount paid by the plan, amount of co-payment/co-insurance paid, and other data. In a transaction *with* the use of the subsidy, *the information transmitted to the health benefit provider does not include any disclosure that a subsidy was paid*; the plan member's cost-sharing obligation is simply reported to the benefit provider as having been paid.

92. As F. Everett Neville, chief trade relations officer at Express Scripts, one of the country's largest PBMs told the New York Times in January 2011, "[t]he payer doesn't know, and the P.B.M. doesn't know . . . We have no ability to stop it and no ability to prohibit it."

93. Here, defendants hired unnamed co-conspirators Opus Health and PSKW to administer its co-pay subsidy programs.

1. Until recently, OPUS Health administered the Crestor and Nexium co-pay subsidy programs for AstraZeneca.

94. Until recently, OPUS Health administered the Crestor and Nexium co-pay subsidy programs. OPUS Health is not named as a defendant in this action but is an unnamed co-conspirator for purposes of and RICO and antitrust violations.

95. OPUS Health advertises that it "pioneered the co-pay assistance space" and that it has "the most extensive industry and product knowledge, providing innovative co-pay assistance, voucher, and patient adherence programs for over 10 years."²⁹ The company "partners with large and specialty pharmaceutical companies to design and implement industry leading patient co-pay assistance and medication adherence programs" that it claims have "measurable, proven outcomes."³⁰

²⁹ <http://www.opushealth.com/manufacturer/programs.aspx> (last visited Mar. 5, 2012).

³⁰ <http://www.opushealth.com/manufacturer/who.aspx> (last visited Mar. 5, 2012).

96. According to OPUS Health, it has implemented and managed over 1,000 programs and currently administers over 250 programs for 7 of the top 10 pharmaceutical companies. It boasts that “[o]ver 99.5% of [its] co-pay cards or vouchers are processed flawlessly” at over 60,000 pharmacies in its network, and it claims to be the only co-pay card administrator “that has never had a program refused or turned off” by pharmacy.³¹ OPUS Health’s pharmacy network includes retail pharmacies in all fifty states, with the greatest concentration in New York, New Jersey, Pennsylvania, Florida and California.

97. Cegedim Relationship Management, OPUS Health’s parent company, tells pharmaceutical companies that OPUS Health’s co-pay cards “help[] level the playing field with other brands and generic products, mitigating the possibility of product substitution at the pharmacy.”

98. OPUS Health offers a family of products called “*SmartTools*” to maximize the effectiveness of its co-pay card programs. These include:

- an online “Specialty Pharmacy Portal” that enables pharmacists to generate “virtual co-pay cards”;
- a “Print on Demand” service that allows doctors to print co-pay cards directly;
- a “Pharmacy Direct” system through which a copy of the co-pay card is faxed directly to the pharmacist and attached to the prescription bag that the patient receives when he or she picks up a prescription;
- “Mobil Interactive Messaging” that sends patients text messages reminding them to refill their prescriptions and use their co-pay savings cards;
- “Interactive Pharmacy Outreach” that “allows for targeting and messaging patients in real time based on prescription history,” with messages that come from “the trusted ‘voice of the pharmacy’”; and

³¹ <http://www.opushealth.com/manufacturer/programs.aspx> (last visited Mar. 5, 2012).

- a “DebitRx®” portal to validates patient eligibility and product information at the point-of-care.³²

99. On Cegedim Relationship Management’s website, OPUS Health provides a series of case studies designed to show prospective members how its services can (1) increase patient acquisition and market share, (2) overcome managed care reimbursement barriers to increase new brand starts, and (3) increase market share and persistence.

100. In one case study, OPUS Health describes how its savings cards can “bridge the co-pay gap” for brand manufacturers facing otherwise facing “stiff competition.”³³ In the case study, co-pay reduction cards, which were distributed to patients by their doctors and activated by telephone, offered \$10 off a patient’s co-pay for three uses. During the four-month test period, OPUS Health reported that 722 patients opted into the program, with 78% redeeming the card and 54% using it two or more times. The drug manufacturer’s new brand start share for the product increased by a weighted average of 15.8 share points over the pre-promotion period.

101. On October 17, 2005, a patent application was filed with the U.S. Patent and Trademark Office, listing OPUS Health LLC as assignee and seeking a patent covering a method for processing co-pay subsidy cards.³⁴

102. The patent application describes how co-pay cards function just like health insurance cards, and how the co-pay subsidies offered in connection with the cards are processed by the pharmacy just as if they are secondary health insurance:

ABSTRACT . . . [T]he cards have on them the same indicia as a standard health insurance card, although they are not issued by a health insurance provider. When the card is presented to a pharmacy, the health insurance indicia allows the pharmacy to

³² <http://crm.cegedim.com/solutions/usa-marketing/patient-co-pay/smart-tools/Pages/default.aspx> (last visited Mar. 5, 2012).

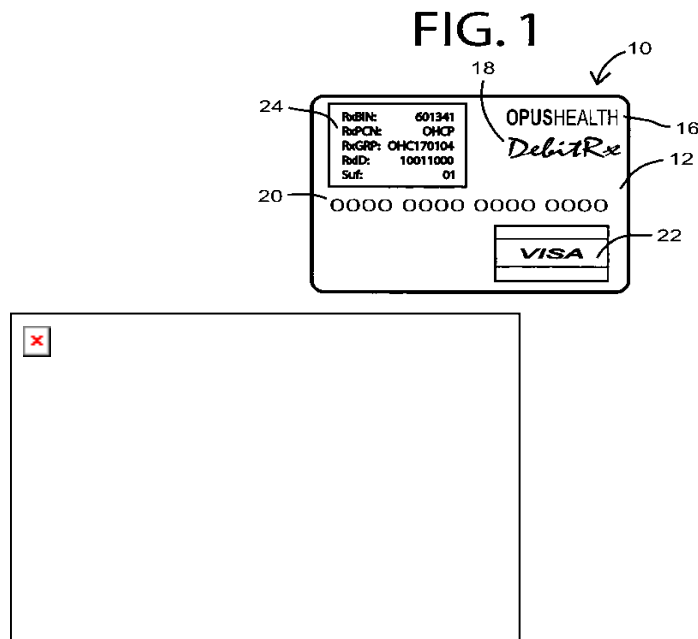
³³ <http://crm.cegedim.com/solutions/usa-marketing/patient-co-pay/Documents/Increasing%20Market%20Share%20and%20Persistence.pdf>.

³⁴ U.S. Patent Application No. 11/252,042 (published Apr. 20, 2006).

‘adjudicate’ the card, through the standard network, whereby the program administrator will instantly activate the card, if necessary, and provide value to the card, by funding the debit account associated with the card, whereby the card can be used immediately as a standard debit card in payment for the prescription which was filled.

* * *

[0039] . . . [T]he system and method of the present invention have been designed so that the card **10** is treated like an insurance prescription card in that it contains the required data, shown at **24** in FIG. 1. In particular, *as far as the pharmacy computer is aware, the information **24** on the card **10** is treated as yet another insurance card.*³⁵



103. The patent application describes how the patient’s primary insurance coverage is adjudicated in an electronic transaction that occurs prior to, and is completely separate from, the “pseudo-adjudication” used to process the co-pay card:

[0038] . . . [T]he networking of pharmacy computers to insurance company or prescription benefit managers’ computers conducted over one or more of the networks which provide such service, which currently include WebMD, eRx Networks, and NDC. Thus, it has been standard practice for some time for pharmacy personnel to adjudicate prescriptions by entering the patient insurance identification information, doctor information, and the specific

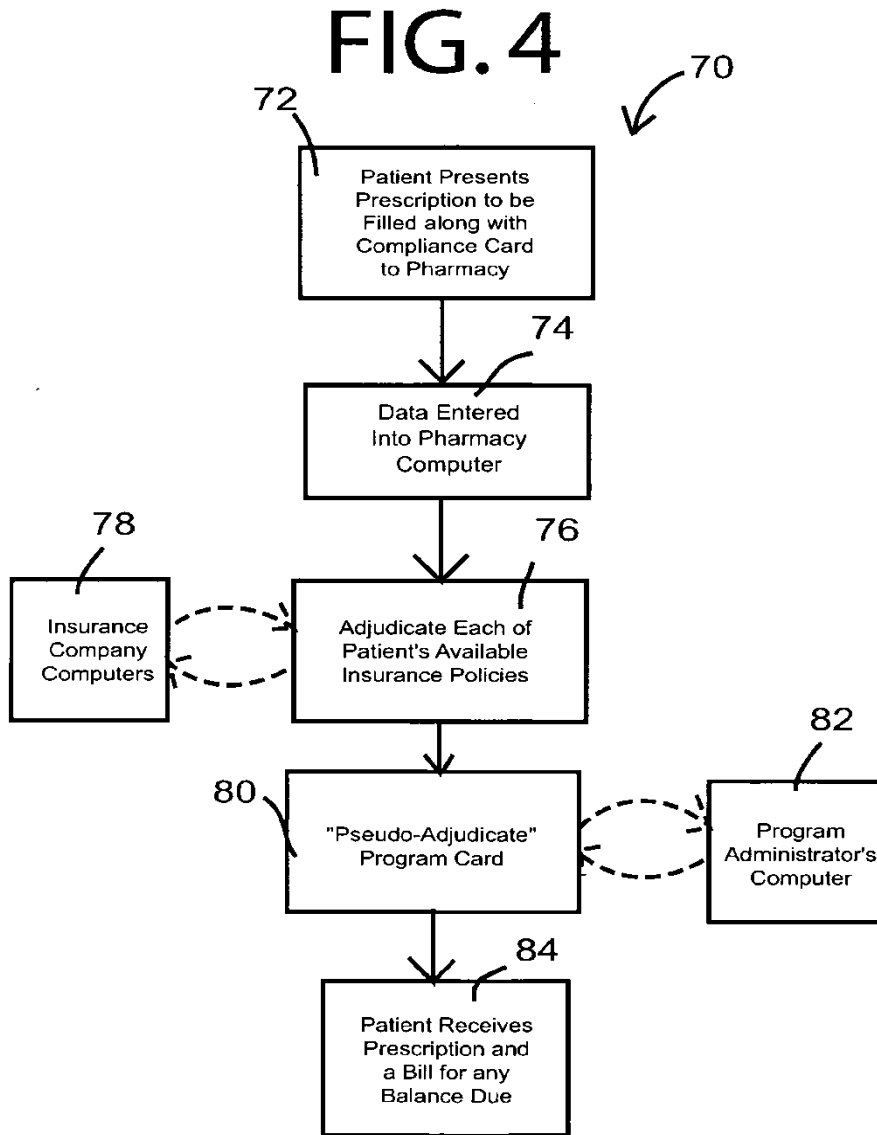
³⁵ *Id.* (emphasis added).

prescription into their computer system, *which then communicates over a network to the insurance company computer*. The result of that communication is that an authorization is provided by the insurance company's computer to the pharmacy confirming the validity of the patient's coverage and authorizing a particular payment to the pharmacy based on such coverage. In that it is not unusual for a patient to have multiple coverage ... *the pharmacy computers are able to communicate with multiple insurance company computers* to obtain verification and funding from the primary company, and then the secondary company, etc., ultimately exhausting the available coverage for the particular prescription and leaving a balance which is then due from the patient as his "co-pay."

* * *

[0039] . . . Accordingly, from the perspective of the pharmacy computer system, step **80** is simply handled as one more adjudication in the process, except that *this step 80 is actually a "pseudo-adjudication" is [sic] handled with the program administrator's computer 82, rather than with one of the insurance company's computers 78.*³⁶

³⁶ *Id.* (emphasis added).



2. PSKW currently administers the Crestor and Nexium co-pay subsidy programs for AstraZeneca.

104. PSKW currently administers the Crestor and Nexium co-pay subsidy programs for AstraZeneca. PSKW is *not* named as a defendant in this action but is an unnamed co-conspirator for purposes of RICO and antitrust violations.

105. On the home page of its website, PSKW boasts that it “works side by side with biopharmaceutical marketers to help build brand loyalty to their brands. Our laser focus on building brand loyalty provides our clients with unmatched advantages.”³⁷

106. Namely, PSKW tailors programs to build brand loyalty through the use of “CoPay assistance” which “generate[s] better response rates.”³⁸

107. One of the programs PSKW touts on its website is its “Automatic Point of Sale Couponing,” which it describes as a co-pay subsidy program:

And for those brands that want to automatically apply a CoPay reduction for their patient population, we provide vouchers on demand – a CoPay reduction service provided at retail to each and every filled subscription. This provides the manufacturer with another vehicle and venue to reach the patient with a CoPay assistance offer, just in case the patient has not received an offer through their physician. Being able to reach the patient at the point of sale could be a critical time if there is a chance that the cost of filling the prescription is too high or if the patient is comparing the brand name option vs. a generic alternative.³⁹

108. PSKW’s focus on generic drugs as alternatives to higher-cost brand-name drugs drives most of its innovations. “[G]iven the rash of patent expirations faced by the pharmaceutical industry, there is a heightened degree of interest in shifting focus from new customers to existing customers — a win-win scenario as both patients and pharmaceutical companies benefit in multiple ways from greater medication adherence.”⁴⁰

109. “Medication adherence” (or the continued use of a name brand drug when a generic has entered the market) is accomplished by “leverag[ing] proprietary technology to

³⁷ www.pskw.com.

³⁸ www.pskw.com/what-we-do/adherence-solutions/.

³⁹ *Id.*

⁴⁰ Press Release, PSKW, PSKW and HealthPrize Partner to Provide Comprehensive Suite of Medication Loyalty, Adherence Solutions to Pharmaceutical Companies (June 16, 2011), *available at* <http://www.pskw.com/company-news/june-16-2011/>.

provide digital messaging and communication at critical points in a patient’s treatment” through the use of devices like “PSKW’s co-pay reduction cards delivered at the point of prescription to drive initial script fill.”⁴¹

110. This “proprietary technology” was supplemented with PSKW’s purchase of Touch Tone Media, Inc. (“Touch Tone”) in April 2006.

Touch Tone spent several years and expended substantial amounts of money to develop a confidential and proprietary method for activating and funding a debit card that could only be used for the intended product. The method that Touch Tone developed involved using the pharmacy adjudication process, which is a national payor network that links pharmacies and the major payors of pharmaceuticals. . . . This new payment method that Touch Tone developed involved linking the national payor network described above with the banking industry.⁴²

111. This technology proved to be quite successful in the development of co-pay subsidy programs, allowing PSKW to “work[] with major pharmaceutical companies, providing proprietary marketing concepts and technology that enables insured prescription patients to obtain their medications with little or no co-pay costs.”⁴³

112. PSKW boasts that its co-pay programs “build brand trial, persistence, and compliance,” successfully edging-out competition from generic drugs.

H. Health benefit providers do not know, and cannot know, when defendants subsidize their members’ co-pays.

113. Health benefit providers are generally aware that drug companies offer co-pay subsidy programs. But health benefit providers do not know, and cannot know, which of the

⁴¹ *Id.*

⁴² *PSKW, LLC v. McKesson Specialty Arizona, Inc.*, No. 602921/07, Second Amended Complaint (Sup. Ct. N.Y. Jul. 16, 2008). PSKW is currently suing McKesson Specialty Arizona, Inc. for misappropriating trade secrets developed by Touch Tone after Touch Tone and McKesson signed a mutual non-disclosure agreement prior to entering into a partnership to develop a co-pay reimbursement program. This was prior to PSKW’s purchase of Touch Tone and all of its tangible and intangible assets.

⁴³ Press Release, PSKW, PSKW Expands its Lawsuit Against McKesson to Seek Assignment of McKesson’s Patent Application (Sept. 1, 2011), *available at* <http://www2.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/09-01-2008/0004876349&EDATE=>.

prescriptions that they have paid for have been subsidized. Pharmacists process subsidies as instructed by the defendants and its co-conspirator administrators, and they do not tell health benefit providers or PBMs when a prescription has been subsidized. Defendants, however, possess detailed records of each and every subsidized prescription. The extent of the injury to Carpenters and the classes can easily be determined through discovery of defendants' co-pay subsidy program records.

I. Defendants' co-pay subsidy programs intentionally interfere with the relationship between health benefit providers and their members.

114. By providing undisclosed kickbacks to reduce or eliminate the cost-sharing mechanism in thousands of health insurance contracts for widely used maintenance prescription drugs, defendants unfairly undermine health benefit providers' best attempts to control prescription drug costs. Pharmacy and Therapeutics ("P&T") committees arrive at formulary placement decisions after considerable decision-making, in an effort to address overall prescription drug costs as a burden on the delivery of quality health care. Even small co-pay subsidies meddle with the cost share balance so carefully struck by P&T committees in formulary tier structures and cost containment provisions in prescription drug benefit plans. Defendants offer such sweeping bribes that it often effectively reduces the co-pay for its branded drugs to *less* than the average co-pay for therapeutic or AB-rated generic alternatives, thereby completely neutralizing health benefit providers' contractual tiered formulary structure.

115. Defendants intend to interfere with health plans' cost-sharing provisions. Before 2005, drug companies regularly offered patients vouchers or coupons for a free prescription of a particular brand name drug. These coupons curried favor with patients but required the manufacturer to absorb the cost of the entire prescription. According to PSKW, the ability to promote brand loyalty by offering the patient a discount while still having the health benefit

provider pay for the majority of the prescription was the key benefit of co-pay card subsidy programs:

At the first Pfizer meeting, Touch Tone's President gave a presentation with respect to Touch Tone's new method, focusing on the benefits of the method, particularly insofar as its ability to *enable the manufacturer to provide a benefit to the patient*, thereby promoting brand loyalty, *while at the same time incurring the cost **only** of the co-pay reimbursement and **not** of the entire cost of the prescription*. Under the inferior loyalty programs offered by other providers, including defendants, vouchers were provided to the patient, who then received free therapy, *with the resulting loss to the manufacturer of the entire cost of the prescription*.⁴⁴

116. The co-pay subsidy kickbacks also force other potential short or long-term changes in available prescription drug coverage. Without a means of enabling cost *sharing* (and make no mistake about it, defendants' co-pay subsidy programs prevent plans and their members from agreeing to effective sharing programs), plans are left to consider wholesale cost *shifting* under which the benefit provider pays *none* of the cost of a branded drug, and the member pays *all* of the cost, when alternatives to a branded drug may exist. At base, defendants have unfairly, deceptively and improperly interfered with health insurance providers' ability to effectively contract for appropriate cost-sharing provisions in insurance contracts.

117. Finally, as described above, the co-pay subsidy kickbacks are an unlawful form of secondary health insurance.

J. Defendants' co-pay subsidy programs involve misrepresentations sent via mail and the wires.

1. Defendants could not run its programs without using the mail and wires.

118. Defendants make individuals aware of its respective co-pay subsidy programs through the mail and wires. Defendants advertise its co-pay subsidy programs on the Internet, splashing links across websites devoted to its brand name drugs. Defendants advertise its co-pay

⁴⁴ Emphasis added.

subsidy programs in magazines and on network television: as an example, the September 19, 2011 issue of Newsweek featured a color advertisement inviting readers to “[l]earn how to SAVE ON CRESTOR” and “[p]rint out [their] CRESTOR Savings Card at CRESTOR.com/savings.”

119. Defendants have individuals sign up for its programs via the wires. Most patients sign up to participate in the programs online, filling out information that is transmitted to the defendants via the Internet.

120. Defendants send the physical co-pay cards to individuals, doctors, and pharmacies via the mail.

121. The co-pay subsidy enterprises do, in fact, use the mail and wires to implement these programs. Defendants and its co-conspirators use the wires to have the pharmacy contact the administrator about the number of subsidized prescriptions filled and the amount subsidized for each prescription, and the administrator in turn contacts the manufacturer and communicates the subsidy information to the manufacturer.

122. Defendants also use the mail and wires to send money to the administrators, and the administrators send money to the pharmacies to effectuate reconciliation and reimburse the pharmacy for recognizing the co-pay subsidies.

123. These communications between pharmacies, the administrators, and the defendants occur tens of thousands of times per year. Defendants and its co-conspirators possess information about the specific dates of transactions, which defendants have withheld from health benefit plans.

2. Defendants convey two distinct misrepresentations via the mail and wires.

124. Defendants and its co-conspirators make misrepresentations via the wires at the time of the point of sale transaction — that is, when the member presents the co-pay card at the

pharmacy — when, as instructed by the defendants, the pharmacist electronically charges the health benefit provider the full benchmark price without accounting for the existence of co-pay subsidies. These transactions necessarily involve the use of the wires.

125. Defendants make additional misrepresentations via the mail and wires when defendants report benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays. These transactions necessarily involve the use of the mail and wires.

VI. CLASS ALLEGATIONS

126. Carpenters brings this action pursuant to Federal Rule of Civil Procedure 23, on behalf of itself and two national classes (one for each of the programs discussed above) defined as:

All entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of a co-pay subsidy drug prescribed to natural persons covered by such contract, policy, or plan, and who paid for at least one prescription for Crestor and Nexium that was subsidized by defendants' co-pay subsidy program(s).

127. The class periods run from when defendants started offering the Crestor and Nexium co-pay subsidy programs until defendants stop offering the programs. The precise period will be identified through discovery.

128. Excluded from the classes are (i) defendants, defendants' legal representatives, officers, directors, assignees, predecessors, and successors, (ii) federal and state governmental entities administering prescription drug programs under Medicare, Medicaid, and or other federally or state-sponsored programs, and (iii) counsel for plaintiff Carpenters and the classes' self-funded health benefit plans (if any).

129. All class members have suffered, and will continue to suffer, harm and damages as a result of defendants' unlawful and wrongful conduct.

130. Defendants' co-pay subsidies are specifically targeted to undermine the cost-share provisions in those contracts.

131. Class members can be precisely determined from defendants' records, the records of the administrators of defendants' co-pay subsidy programs, and pharmacy records. Members of the classes themselves are unable to identify the subsidized prescriptions. However, defendants possess information about the subsidized prescriptions, including the name and specific identifying information about each participating member and the pharmacy where the prescription was filled. The pharmacy has a record of both the amount of subsidy and the individual's health plan. The administrators also have this information, as well as the accumulated results of the programs through all pharmacies. No uninjured parties will be included within the classes because each member can be determined with specificity, based on actual transactional data.

132. The fact of injury or damages to each class member can also be reasonably estimated from existing data. Aggregate damages to the classes as a whole can reasonably be estimated from existing data, and commonly-used mechanisms by which to allocate that award among class members exist.

133. The classes consist of thousands of private health benefit providers. These providers are geographically dispersed throughout the United States. The disposition of all claims in a single action will substantially benefit all parties and the Court.

134. Plaintiff Carpenters is the proposed class representative for both classes.

135. The claims of Carpenters are typical of the claims of the classes. Carpenters purchased drugs on behalf of its members whose cost-share obligations were subsidized by defendants. Carpenters, like all class members, paid for too many co-pay subsidy drug

prescriptions as a result of defendants' subsidies. Carpenters will fairly and adequately protect the interests of the class. Carpenters has retained counsel with substantial experience prosecuting nationwide third party payor class actions. Carpenters and its counsel are committed to vigorously prosecuting this action on behalf of the class and have the financial resources necessary to do so.

136. The factual and legal issues regarding defendants' alleged misconduct are common to all class members and represent a common thread of misconduct resulting in injury to Carpenters and the classes. Common questions of law and fact include:

- a. Whether defendants engaged in a course of conduct that improperly increased plaintiff's and other class members' drug costs;
- b. Whether defendants engaged in kickback schemes to increase plaintiff's and other class members' drug costs;
- c. Whether defendants engaged in a pattern of deceptive and/or fraudulent activity intended to defraud plaintiff and other members of the classes;
- d. Whether defendants formed enterprises for the purpose of effectuating its fraudulent schemes;
- e. Whether defendants used the U.S. mails and interstate wire facilities and commerce to carry out these fraudulent schemes;
- f. Whether defendants engaged in conduct that violated the federal racketeering laws as alleged herein;
- g. Whether defendants engaged in conduct that violated federal antitrust laws as alleged herein;

- h. Whether plaintiff and the other members of the classes were injured by the conduct of defendants and, if so, the appropriate class-wide measure of damages; and
- i. Whether plaintiff and the other members of the classes are entitled to injunctive relief.

137. Prosecution of separate actions by individual class members would create the risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for defendants.

138. Defendants have acted on grounds generally applicable to all class members in that defendants' anticompetitive and fraudulent actions uniformly impacted all class members. Accordingly, injunctive relief is necessary to protect all class members from further injury.

139. Plaintiff knows of no difficulty that would prevent this case from being maintained as a class action. A class action is the superior method for fairly and efficiently adjudicating this controversy. The cost of litigating a single action would prevent most class members from bringing suit individually. Class action treatment will, among other things, allow a large number of similarly situated entities to prosecute their common claims in a single forum, thus avoiding the unnecessary duplication of resources that numerous individual actions would require. Moreover, class action treatment allows injured payors, including smaller plans with limited means, to seek redress on claims that might be impracticable to pursue individually. Thus, absent a class action, there would be no remedy at law for thousands of injured entities. And absent a class action, there would be no mechanism for imposing uniform equitable injunctive relief to the class as a whole.

VII. CAUSES OF ACTION

COUNTS ONE AND TWO SUBSTANTIVE RICO VIOLATION (18 U.S.C. § 1962(c))

140. These Counts allege substantive violations of RICO (as provided in 18 U.S.C. § 1962(c)), relating to the co-pay subsidy programs described above, and is asserted against defendants on behalf of plaintiff Carpenters and the classes.

141. COUNT ONE is asserted against defendant AstraZeneca Pharmaceuticals LP for the Crestor co-pay subsidy program. The Crestor co-pay subsidy enterprise is an association-in-fact comprised of defendant AstraZeneca Pharmaceutical LP and unnamed co-conspirators PSKW and OPUS Health.

142. COUNT TWO is asserted against defendant AstraZeneca LP for the Nexium co-pay subsidy program. The Nexium co-pay subsidy enterprise is an association-in-fact comprised of defendant AstraZeneca LP and unnamed co-conspirator PSKW and OPUS Health.

143. These enterprises are referred to collectively as the “co-pay subsidy enterprises.” The drugs Crestor and Nexium are referred to collectively as the “subsidized drugs.” OPUS Health and PSKW are referred to collectively as the “administrators.”

144. Plaintiff, members of the classes, defendants, and the unnamed co-conspirators are all “persons” as defined by 18 U.S.C. § 1961(3).

A. Defendants and its respective co-conspirators formed association-in-fact RICO enterprises.

145. For purposes of this claim, the RICO co-pay subsidy enterprises alleged herein are associations-in-fact within the meaning of 18 U.S.C. § 1961(4). Defendants and its co-conspirator administrators, including their directors, employees, and agents, formed association-in-fact enterprises. These co-pay subsidy enterprises are each an ongoing and continuing

business organization consisting of both corporations and individuals that are and have been associated for the common or shared purpose of maximizing sales of subsidized drugs by unlawfully interfering with cost-sharing provisions.

146. Within each co-pay subsidy enterprise there are contractual relationships, financial ties, and continuing coordination activities between defendants and its co-conspirator administrators.

147. On information or belief, members of each co-pay subsidy enterprise have communicated repeatedly over the course of several years to carry out their common purposes, and have entered into, monitored, and enforced contractual and/or agency arrangements regarding payment and the delivery of services. Defendants hired the administrators to carry out the programs.

B. Each co-pay subsidy enterprise engaged in and affected interstate commerce.

148. Each co-pay subsidy enterprise engaged in and affected interstate commerce because they involved thousands of transactions at hundreds of pharmacies all over the country and are attendant to defendants' marketing, distribution, and sale of the subsidized drugs across state boundaries and throughout the United States.

149. During the class period, the illegal conduct and wrongful practices carried out by members of each co-pay subsidy enterprise (including defendants and the administrators) were effectuated by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products, and funds through the U.S. mails and interstate wire facilities. In particular, administrators transmitted pharmacy data to defendants, and defendants transmitted funds to the administrators, who transmitted funds to the pharmacies.

C. Defendants associated with its respective co-pay subsidy enterprises.

150. The nature of the co-pay subsidy schemes required defendants to form and participate in enterprises. Defendants hired its co-conspirator administrators and monitored and enforced this contractual arrangement regarding payment and the delivery of services. Each of these actions was necessary to, or helpful in, each co-pay subsidy enterprise's ability to carry out its goal of interfering with plaintiff and class members' cost-sharing provisions and causing plaintiff and class members to be charged an inflated reimbursement rate for subsidized prescriptions.

D. The co-pay subsidy enterprises engaged in a pattern of racketeering activity.

151. Defendants conducted and participated in the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341 (mail fraud) and 18 U.S.C. § 1343 (wire fraud).

1. The co-pay subsidy enterprises engaged in schemes to defraud.

152. The co-pay subsidy enterprises engaged in intentional schemes to defraud plaintiff and the classes by interfering with their cost-sharing provisions, causing them to pay for prescriptions of the subsidized drugs that they would not have otherwise paid for, and causing them to pay an inflated rate for each subsidized prescription. These transactions necessarily involve the use of the wires.

153. The co-pay subsidy enterprises engaged in separate but related intentional schemes to defraud plaintiff and the classes by causing misrepresentations to be made via the wires at the time of the point of sale transaction — that is, when the member presents the co-pay card at the pharmacy — when, as instructed by the defendants, the pharmacist electronically charges the health benefit provider the full benchmark price without accounting for the existence of co-pay subsidies. These transactions necessarily involve the use of the wires.

154. The co-pay subsidy enterprises engaged in separate but related intentional schemes to defraud plaintiff and the classes by reporting benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays. These transactions necessarily involve the use of the mail and wires.

155. Defendants knew that entities like plaintiff and members of the classes have cost-sharing programs to reduce the use of brand drugs by their plan members. The purpose and intent of defendants' co-pay subsidy schemes was to overcome such restrictions on brand drug purchases and to cause plaintiff and the classes to pay for more of the subsidized drugs at artificially inflated prices.

2. The co-pay subsidy enterprises used interstate communications systems to carry out these schemes.

156. The nature of these schemes necessarily required members of each co-pay subsidy enterprise to communicate directly and frequently by the U.S. mails and interstate wire facilities.

157. Many of the precise dates of the co-pay subsidy enterprises' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to defendants' records. An essential part of the successful operation of the co-pay subsidy enterprises was defendants' ability to conceal the use of subsidies from Carpenters and the classes at the point of sale.

158. During the class period, defendants exerted control over the co-pay subsidy enterprises, and in violation of the § 1962(c) of RICO, it conducted and participated in the conducts of the affairs of the co-pay subsidy enterprises, directly or indirectly, in the following ways:

- i. Defendants conceived of and implemented the unlawful co-pay subsidy programs;

- ii. Defendants directly controlled the creation and distribution of marketing, sales, and other materials used to inform patients and physicians about the unlawful co-pay subsidy programs;
- iii. Defendants set the terms of the programs, including eligibility criteria, amount of subsidy, and number of subsidies;
- iv. Defendants caused administrators to administer the programs without informing health benefit plans about the subsidies; and
- v. Defendants instructed and caused pharmacies to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions by instructing the pharmacy to process the co-pay card as though it were a form of secondary insurance.

159. Defendants' pattern of racketeering likely involved tens of thousands of separate instances of use of the U.S. mails or interstate wire facilities to carry out the unlawful co-pay subsidies. Each of these fraudulent mailings and interstate wire transmissions and/or each transaction to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). These violations constitute a "pattern" of racketeering activity within the meaning of 18 U.S.C. § 1961(5) in which defendants intended to defraud Carpenters and members of the classes

E. The unlawful activity proximately injured plaintiff and the classes.

160. Defendants' participation in the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity has directly and proximately caused plaintiff Carpenters and members of the classes to be injured in their business or property. Plaintiff Carpenters, members of the classes, and others reasonably relied upon a belief that their members were paying their share of prescription drug costs (as determined by the cost-sharing provisions of their particular

health plans) and that pharmacies were reporting and charging a reimbursement rate that accurately reflected the price defendants actually charged for the subsidized drugs.

161. Defendants profited directly from the co-pay subsidy schemes in the form of increased sales of the subsidized drugs that plaintiff and the classes would not otherwise have purchased but for defendants' interference with its cost-sharing programs. As a direct and proximate result of defendants' overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(c), plaintiff Carpenters and the classes have been and are continuing to be injured in their business or property.

162. Plaintiff Carpenters and members of the classes were injured in their property by reason of these violations because plaintiff and members of the classes have paid for an increased number of prescriptions for the subsidized drugs as a result of the co-pay subsidy enterprises' substantive RICO violations. By reason of the unlawful acts engaged in by each co-pay subsidy enterprise, plaintiff Carpenters and the classes have suffered ascertainable loss and damages. These injuries were directly and proximately caused by defendants' racketeering activity.

163. Under § 1964(c) of RICO, defendants are liable to plaintiff Carpenters and members of the classes for three times the damages sustained, plus the cost of bringing suit and reasonable attorneys' fees.

**COUNTS THREE AND FOUR
CONSPIRACY TO VIOLATE RICO
(18 U.S.C. § 1962(d))**

164. These Counts allege conspiracies to violate of RICO (as provided in 18 U.S.C. § 1962(d)) relating to the co-pay subsidy programs described above, and are asserted against defendants on behalf of plaintiff Carpenters and the classes.

165. COUNT THREE is asserted against defendant AstraZeneca Pharmaceutical LP for the Crestor co-pay subsidy program. The Crestor co-pay subsidy enterprise is an association-in-fact comprised of defendant AstraZeneca Pharmaceutical LP and unnamed co-conspirators PSKW and OPUS Health.

166. COUNT FOUR is asserted against defendant AstraZeneca LP for the Nexium co-pay subsidy program. The Nexium co-pay subsidy enterprise is an association-in-fact comprised of defendant AstraZeneca LP and unnamed co-conspirators PSKW and OPUS Health.

167. These enterprises are referred to collectively as the “co-pay subsidy enterprises.” The drugs Crestor and Nexium are referred to collectively as the “subsidized drugs.” OPUS Health and PSKW are referred to collectively as “administrators.”

168. Section 1962(d) of RICO provides that it “shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section.” Defendants have violated Section 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of these ongoing conspiracies was to conduct or participate in, directly or indirectly, the conduct of the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity.

169. Defendants adopted the goal of furthering or facilitating the criminal endeavors of the co-pay subsidy enterprises minimally by agreeing to facilitate some of the acts leading to the substantive offenses, and directly by engaging in numerous overt and predicate fraudulent racketeering acts in furtherance of each conspiracy, as described above.

170. Defendants not only agreed to the objectives of the 18 U.S.C. § 1962(d) violations of RICO by conspiring to violate 18 U.S.C. § 1962(c), but was aware that its ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

171. By hiring administrators to carry out the co-pay subsidy schemes, defendants engaged in overt acts in furtherance of the schemes as well as actual predicate violations of mail or wire fraud. As a direct and proximate result of defendants' overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), plaintiff Carpenters and members of the classes have been and are continuing to be injured in their business or property.

172. Plaintiff Carpenters and members of the classes were injured in their property by reason of these violations in that plaintiff and members of the classes have paid for an increased number of prescriptions for the subsidized drugs as a result of the co-pay subsidy enterprises' conspiracies to violate 18 U.S.C. § 1962(c).

173. By reason of the unlawful acts engaged in by each co-pay subsidy enterprise, plaintiff Carpenters and the classes have suffered ascertainable loss and damages. These injuries were directly and proximately caused by defendants' racketeering activity.

174. By virtue of these violations of 18 U.S.C. § 1962(d), defendants are liable to plaintiff Carpenters and the classes for three times the damages sustained, plus the cost of this suit and reasonable attorneys' fees.

COUNTS FIVE AND SIX
COMMERCIAL BRIBERY IN VIOLATION OF ROBINSON-PATMAN ACT
(15 U.S.C. § 13 (c))

175. These Counts allege commercial bribery in violation of the Robinson-Patman Act (as provided in 15 U.S.C. § 13 (c)), relating to the co-pay subsidy programs described above, and are asserted against AstraZeneca on behalf of plaintiff Carpenters and the classes.

176. COUNT FIVE is asserted against defendant AstraZeneca Pharmaceutical LP for the Crestor co-pay subsidy program.

177. COUNT SIX is asserted against defendant AstraZeneca LP for the Nexium co-pay subsidy program.

178. These programs are referred to collectively as the “co-pay subsidy programs.” The drugs Crestor and Nexium are referred to collectively as the “subsidized drugs.”

179. Section 2(c) of the Robinson-Patman Act prohibits the payments by drug manufacturers to, or on behalf of, individual insureds to eliminate or reduce their personal obligations under prescription drug plans’ cost-sharing plans. The relevant part of the statute makes it unlawful for any person engaged in commerce to:

(1) pay (or receive)-

(a) anything of value as a commission, brokerage, or other compensation, or

(b) by allowance or discount in lieu of brokerage, *except* for services rendered in connection with a sale or purchase of goods,

(2) when the payment is made to (or by)

(a) the other party to the transaction, or

(b) an agent, representative or other intermediary where the intermediary is

(i) acting for or in behalf of, or

(ii) subject to the direct or indirect control of

(iii) any party to the transaction other than the person by whom the compensation is paid.⁴⁵

180. Generally, these provisions of the Robinson-Patman Act bar commercial bribery, *i.e.*, they prohibit a person from paying off fiduciaries, agents or other intermediaries who control purchasing decisions to be paid for by another. Here, defendant is a “person” making payment of something of value: defendant pays an individual insured to choose a subsidized drug that is paid

⁴⁵ 15 U.S.C. § 13.

for by the individual's health benefit provider. Paying individuals who receive prescription drug benefits pursuant to plans offered by private health benefit providers qualifies as a violation of Section 2(c) of the Robinson-Patman Act because the subsidies are "anything of value" which are both (i) paid as "compensation" for purchasing the branded drug, and (ii) as a "discount in lieu of brokerage." But members do not know these co-pay subsidies are bribes.

181. Individual insureds who accept rebates under defendants' co-pay subsidy programs qualify as "agent[s], representative[s] [and] "other intermediar[ies]" because, pursuant to the terms of their agreements with their health benefit providers, they both (i) act on behalf of their health benefit providers in having substantial control in the choice of which medications will be paid for by the health benefit providers and, (ii) under the terms of the agreements with their health benefit providers, act subject to their health benefit providers' direct and indirect control in seeking payment for the selected medication through the terms of their plans.

182. Defendants offer these co-payment subsidies to privately-insured plan members in order capture the large payments by private health benefit providers that accompany the relatively modest co-payments made by the individual members. By drastically reducing or eliminating the increased cost-sharing obligation, defendants increase sales of subsidized drugs to the detriment of health benefit plans. Health benefit providers (including Carpenters) invest a great deal of actuarial resources to provide incentives for their members to choose less expensive prescription drug therapy that works as well as pricier drugs. Defendants' co-pay subsidy programs provide illegal inducements to members to choose more expensive drugs, to the detriment of prescription drug plans provided by Carpenters and members of the classes.

183. As a result, defendants' co-pay subsidy programs result in injury to Carpenters and the classes because the payments result in more purchases of subsidized drugs by plaintiff and the classes than would have been made absent the illegal inducements.

VIII. DEMAND FOR JUDGMENT

184. WHEREFORE, plaintiff Carpenters, on behalf of itself and the proposed classes, respectfully requests that the Court:

- A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the classes, and declare plaintiff Carpenters the class representative for both classes;
- B. Enter judgment against defendants in favor of Carpenters and the classes;
- C. Adjudge and decree the acts alleged herein to be unlawful;
- D. Award the classes damages in an amount to be determined at trial;
- E. Award the classes threefold damages pursuant to 18 U.S.C. § 1964(c) and 15 U.S.C. § 15(a);
- F. Award plaintiff and the classes their costs of suit, including reasonable attorneys' fees as provided by law;
- G. Enjoin defendants from offering these or similar co-pay subsidy programs; and
- H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by defendants' unlawful conduct as the Court deems just.

IX. JURY DEMAND

185. Pursuant to Fed. Civ. P. 38, plaintiff, on behalf of itself and the proposed classes, demands a trial by jury on all issues so triable.

Dated: March 19, 2012

Respectfully submitted,

s/ Jeffrey L. Kodroff (JLK4986)
Jeffrey L. Kodroff
SPECTOR ROSEMAN KODROFF & WILLIS PC
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Tel. (215) 496-0300
Fax. (215) 496-6611
jkodroff@srkw-law.com

Steve W. Berman
Barbara A. Mahoney
HAGENS BERMAN SOBOL SHAPIRO LLP
1918 Eighth Ave., Suite 3300
Seattle, WA 98101
Tel. (206) 623-7292
Fax. (206) 623-0594
steve@hbsslaw.com
barbaram@hbsslaw.com

Thomas M. Sobol
Lauren Guth Barnes
Kristen Johnson Parker
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Tel. (617) 482-3700
Fax. (617) 482-3003
tom@hbsslaw.com
lauren@hbsslaw.com
kristenjp@hbsslaw.com

Kenneth A. Wexler
Bethany R. Turke
Dawn M. Goulet
Amy E. Keller
WEXLER WALLACE LLP
55 West Monroe St., Suite 3300
Chicago, IL 60603
Tel. (312) 346-2222
Fax (312) 346-0022
kaw@wexlerwallace.com
brt@wexlerwallace.com
dmg@wexlerwallace.com
aek@wexlerwallace.com

*Counsel for New England Carpenters Health and
Welfare Fund and the class*